MAR 14 2000

K00 0016

510(k) SUMMARY

A. Manufacturer: Barco NV/Display Systems
Theodoor Sevenslaan 106
8500 Kortrijk
Belgium

Submitted By: Ferguson Medical
Consultant to Barco NV

B. Contact Information: Phone: +32(0)56 23 32 11
FAX: +32(0)56 23 3 74

C. Classification Name: System, imaging processing

Common/usual Name: Medical imaging board

Proprietary Name: BarcoMed 5MP2

D. Classification Number: 21 CFR 892.2050/Procode 90LLZ

E. Substantial Equivalence: Barco NV/Display Systems, MeDis 5 MP 5 MegaPixel Medical Diagnostic Display System (K982820), and others.

F. Device Description: The BarcoMed 5MP2 device is a digital imaging board used in medical image processing.

G. Intended Use: The BarcoMed 5MP2 device is intended to be used in the digital processing of medical images to be displayed for review and analysis by trained medical practitioners.

H. Technological Characteristics: The BarcoMed 5MP2 device is a digital imaging board utilized to provide high resolution visualization of digital images.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2000

Barco NV Display Systems
c/o Frank Ferguson
Official Correspondent
Ferguson Medical
P.O. Box 12038
LaJolla, CA 92039-2038

Re: K000016
BarcoMed 5MP2
Dated: December 9, 1999
Received: January 3, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Ferguson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (If known): K000016

Device Name: BarcoMed 5MP2 5 MegaPixel Dual Head Medical Imaging Board

Indications For Use:

The BarcoMed 5MP2 5 MegaPixel Dual Head Medical Imaging Board is intended to be used in the digital processing of medical images to be displayed for review and analysis by trained medical practitioners.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000016

Prescription Use XX OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)